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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,523	09/14/2001	Stewart Cole	05394.0013	4377

7590

12/18/2002

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EXAMINER

JOHANNSEN, DIANA B

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 12/18/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/936,523

Applicant(s)

COLE ET AL.

Examiner

Diana B. Johannsen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6, 8-23 and 25-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-6, 8-23 and 25-33 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

***ELECTION/RESTRICTION***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions that are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-2, drawn to nucleic acids.

Group II, claim(s) 3-6 and 8, drawn to methods of detecting mycobacterial species by nucleic acid amplification.

Group III, claim(s) 9, drawn to kits comprising primers.

Group IV, claim(s) 10, drawn to methods of nucleic acid amplification.

Group V, claim(s) 11, 14-15, and 17, drawn to polypeptides, antibodies, and kits comprising polypeptides and antibodies.

Group VI, claim(s) 12-13 and 27-33, drawn to methods of detecting antibodies.

Group VII, claim(s) 16, drawn to methods of detecting protein.

Group VIII, claim(s) 18-19, drawn to a vaccine.

Group IX, claim(s) 20-23 and 25-26, drawn to methods of detecting mycobacterial species by restriction digestion.

2. The inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. The expression "special technical feature" is defined in PCT Rule 13.2 as

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meaning those technical features that define a contribution that an invention considered as a whole makes over the art. Regarding the relationship of Group I with Groups II-IX, a shared technical feature that is present are sequences that are “deleted from the genome of *M. bovis* BCG/*M. bovis* and present in the genome of *M. tuberculosis*” (see claim 1). However, such sequences were known in the art at the time the invention was made (see, e.g., Brosch et al, Infection and Immunity 66(5):2221-229, entire reference, especially, e.g., p. 2226). As molecules meeting the limitations of Group I do not make a contribution over the art, this feature cannot constitute a special technical feature as defined by PCT Rule 13.2, and unity of invention is therefore lacking.

Further, Groups I-IX do not share another technical feature that might constitute a “special technical feature” as defined by PCT Rule 13.2. The primers of Group III are short nucleic acid molecules that function in, e.g., amplification, and therefore this molecules differ both structurally and functionally from the molecules of Group I, which encode genes and function in, e.g., methods of making protein. The products of Group V, proteins, antibodies, and combinations thereof, are composed of amino acids linked by peptide bonds, and function in, e.g., methods of detection. In contrast, the vaccine of Group VIII requires a “pharmaceutically compatible vehicle” and must function immunologically. The methods of Groups II, IV, VI, VII, and IX each have different effects and steps. The methods of Group II require analysis of sequence to achieve the objective of detection, whereas the methods of Group IV require a step of primer hybridization to achieve the objective of amplification. The methods of Group VI require steps of contacting a biological sample with a protein to achieve the objective of

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antibody detection, while the methods of Group VII require contacting a sample with an antibody to achieve protein detection. The methods of Group IX require a step of restriction digestion to achieve detection. Thus, the inventions of Groups I-IX are not so linked by a special technical feature within the meaning of PCT Rule 13.2 so as to form a single general inventive concept.

### **Election Requirements Applicable to Groups I-IX**

3. **Groups I and V-VIII** each read on numerous patentably distinct genes or gene products. Each of the molecules of claim 1 (as well as the polypeptides transcribed and translated therefrom and the antibodies that specifically bind those polypeptides) has a different structure, as well as different functional properties. The molecules are not obvious variants of one another, and the differing molecules do not share a special technical feature within the meaning of PCT Rule 13.2. Accordingly, a further restriction is applied to each of Groups I and V-VIII. If any of these Groups is elected, Applicant must further elect a single molecule (a single nucleic acid, polypeptide, and/or antibody, as appropriate to the elected Group). Applicant should specifically identify the molecule(s) elected. Regarding Group I, it is noted that if this Group is elected, Applicant may elect (as an alternative to electing a single nucleic acid) a single combination or group of such molecules, as recited in claim 2. The claims of the elected Group will be examined to the extent that they are drawn to the elected molecule(s). **This is not an election of species. Applicant is advised that examination will be restricted to only the elected molecule(s).**

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4. **Groups II-IV and IX** each read on numerous patentably distinct primer pairs. Each primer pair has a different combination of sequences, and amplifies a different genetic region. Accordingly, each primer pair differs both structurally and functionally from each other primer pair. The molecules are not obvious variants of one another, and the different pairs do not share a special technical feature within the meaning of PCT Rule 13.2. Accordingly, a further restriction is applied to each of Groups II-IV and IX. If any of these Groups is elected, Applicant must further elect a single primer pair. Applicant should specifically identify the primer pair elected, including the relevant SEQ ID NOS. The claims of the elected Group will be examined to the extent that they are drawn to the elected primer pair. **This is not an election of species. Applicant is advised that examination will be restricted to only the elected primer pair.**

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

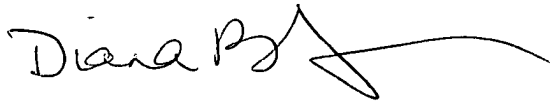
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is

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703/305-0761. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 703/308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703/872-9306 for regular communications and 703/872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-0196.

A handwritten signature in black ink, appearing to read "Diana B. Johannsen", followed by a long, sweeping horizontal line that extends to the right.

Diana B. Johannsen  
December 16, 2002